UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	

SUPPLEMENTAL DECLARATION OF GREGORY K. BELL, PH.D.

April 28, 2006

1. On March 15, 2006, I submitted a declaration in this matter on behalf of Bristol-Myers Squibb Company, Oncology Therapeutic Network Corporation and Apothecon, Inc. (Bell BMS Declaration). I have since been asked to review and respond to certain comments regarding my qualifications as an expert witness that are set forth in Plaintiffs' Memorandum in Opposition to the BMS Defendants' Motion for Summary Judgment (Plaintiffs' Memorandum). Plaintiffs assert that I am "a *de facto* professional witness for the pharmaceutical industry" because of my prior work as a business consultant and as an expert witness on behalf of some of the defendants in this litigation.[1] It is further alleged that I "was an active participant in the fraud challenged here."[2]

2. I take exception to the characterization that I am "a *de facto* professional witness for the pharmaceutical industry." It is true that I have extensive experience as a business consultant and expert witness for a number of pharmaceutical companies, in particular, experience that is directly relevant to my analysis of the issues in this case. As indicated in the Bell BMS Declaration at ¶ 1 and Exhibit A, I am the Group Vice President at CRA International responsible for the global Pharmaceuticals practice, a responsibility I have managed for the past ten years. I am also the Group Vice President responsible for the global Intellectual Property practice, a responsibility I have managed for the last seven years. During my professional career at CRA, I have authored expert reports and provided expert testimony in more than fifty matters, less than half of which involved the pharmaceutical industry. The other matters dealt with medical devices, financial instruments and a broad range of industrial and consumer products including, but not limited to, security systems, sportswear, optical fiber, online commerce and electronics. Most recently, I was widely quoted regarding CRA's survey of the costs incurred by public companies to comply with the reporting requirements

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1 Plaintiffs' Memorandum, p. 22.

2 *Ibid.*

under the Sarbanes-Oxley Act; this work was completed on behalf of the Big Four accounting firms.[3]

3. Plaintiffs' allegation that I "was an active participant in the fraud challenged here" is simply not true. To support their allegation, Plaintiffs selectively quote from slides my staff and I created for several meetings that we had with BMS employees relating to the "Paraplatin Deconversion" project.[4] Plaintiffs misconstrue these documents and misrepresent the substance of my work in this engagement.

4. As discussed in the Bell BMS Declaration at ¶¶ 35–36, BMS retained CRA in 1999 to help formulate business strategy for Paraplatin and Platinol, two of BMS Oncology's branded drugs, in light of the imminent launch of cisplatin, the generic version of Platinol. The project was called "Paraplatin Deconversion" because it addressed the BMS concern that some "at risk" hospitals and community oncology practices would "deconvert," switch back to dispensing cisplatin for economic reasons even though Paraplatin was the more appropriate choice, as it was believed to be clinically superior, better tolerated by patients and required less time to administer than cisplatin.[5]

5. Plaintiffs contend that the phrases "Performance-based Contracting/Pricing," "Acquisition cost and AWP" and "AWP and spread opportunities" in CRA's July 21, 1999 Paraplatin Deconversion discussion outline somehow are evidence of my participation in the alleged AWP fraud.[6] This contention is simply wrong.

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3 See, for example, Reilly, David, "Internal-Control Help Becomes Less Costly," *Wall Street Journal*, April 19, 2006, p. C3.

4 Declaration of Steve W. Berman in Support of Plaintiffs' Memorandum in Opposition to the BMS Defendants' Motion for Summary Judgment and Response of Class Plaintiffs to Local Rule 56.1 Statement of Defendants Bristol-Myers Squibb Company and Oncology Therapeutic Network Corp., Exhibit 57. The CRA documents in Exhibit 57 include a discussion outline dated July 21, 1999 (BMS/AWP/01233108–123), another discussion outline dated August 16, 1999 (BMS/AWP/01233124–147) and the findings and recommendations dated October 13, 1999 (BSM/AWP01233148–184).

5 BMS/AWP/01233174 and BMS/AWP/01233177.

6 Plaintiffs' Memorandum, p. 22.

a. First, I generally use the phrase "Contracting/Pricing" to reinforce for clients that contracting strategy initiatives will have an impact on the realized net price; not to indicate that the product's list pricing strategy is under consideration. In other words, contractual price concessions (like rebates) enhance the incentives of certain cost-conscious customers to purchase the product without lowering the list price paid by other customers.[7]

b. Second, at this early stage in the project, one of the tactics that the project team was considering (hence, one of the topics for discussion at the meeting) was the use of performance-based contracts, which would have required that the customer meet specified sales or share targets to "earn" the price concession. Such contracts might include offering at-risk hospitals and oncology practices rebates based on both Paraplatin purchase volume and Paraplatin's share of total Paraplatin and cisplatin utilization.[8] As noted in the Bell BMS Declaration at ¶ 7c, such a contracting tactic represents appropriate and standard economic behavior; it is an expected and economically rational response to competition.[9] There was no suggestion of manipulating the spread on branded Paraplatin.

c. Third, in this instance, the competition was going to be generic cisplatin. The advantage of generic cisplatin for the physicians at issue was going to be the expected difference between "acquisition cost and AWP" and the

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7 For instance, a contracting strategy initiative might be expected to result in a five percent rebate to those physicians that dispense fifty percent of the product. As a result, those physicians observe a five percent drop in the net acquisition cost for the product and the company observes an average price concession equal to 2.5 percent.

8 BMA/AWP/01233120.

9 The October 13, 1999 final project presentation, "Findings and Recommendations," suggests a possible contract structure for oncology offices with a maximum rebate equal to six percent of WLP, based on the satisfaction of certain performance criteria. (BMS/AWP/01233180–182.) In 2000, the first full year following completion of the Paraplatin Deconversion project, the average price concession on oncology office purchases of Paraplatin remained virtually constant, at 4.9 percent of WLP, as compared to 5.0 percent of WLP in 1999. (Bell BMS Declaration, Exhibit D.)

consequent "spread" opportunities that would become available. I believe the phrases "Acquisition cost and AWP" and "AWP and spread opportunities" referred to the advantage that generic cisplatin would have over Paraplatin. I do not recall any discussion of "spread opportunities" as a BMS strategy and to the best of my knowledge no such strategy was implemented.

d. Fourth, I note that Plaintiffs do not mention the first tactic that was proposed for discussion, namely, that BMS provide "Information and marketing programs that highlight Paraplatin's advantages" over cisplatin, separate and apart from acquisition cost, such as "Tolerability," "Ease of administration" and "Impact on practice profits."[10] As discussed further below, these themes became the centerpiece of the Paraplatin Deconversion project.

6. Plaintiffs also suggest that I took part in the alleged AWP fraud simply because I stated that "Taxol/Paraplatin has higher drug margin per patient treated than current competing regimens" used to treat NSCLC (non-small cell lung cancer) in the August 16, 1999 Paraplatin Deconversion discussion outline.[11] The graphic at issue merely presents my team's conclusions after comparing the cost of competing regimens. Notably, at the time CRA analyzed the drug margin per patient for the regimens used to treat NSCLC, the average price concession to oncology office practices on Paraplatin and Taxol were only 5.0 and 3.6 percent of WLP respectively.[12]

7. Plaintiffs further accuse me of advising "BMS to cover-up its spread-marketing activities" because the August 16, 1999 discussion outline notes "[e]conomic

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10 BSM/AWP/0123118. The impact on practice profits takes into consideration both drug reimbursement and chair time. A longer drug administration time, i.e. a longer chair time, is less profitable for a hospital or oncology practice because the number of infusion chairs limits the number of cancer patients that can be treated at any one time.

11 Plaintiffs' Memorandum, p. 22. Plaintiffs incorrectly cite to BMS/AWP/01233118; the statement is actually at BMS/AWP/01233131.

12 Bell BMS Declaration, Exhibit D.

issues to be discussed in a low key manner" and that there should be "[n]o printed materials."[13] Plaintiffs take these two phrases out of context and fail to mention the rest of the suggestion. The document actually states:[14]

- Economic issues to be discussed in a low key manner
  - No printed materials
  - Respond to physician concern
  - Maintain the "high road"—officially promoting Paraplatin based on efficacy, tolerability and quality of life

Far from advising "BMS to cover-up its spread-marketing activities," it is proposed that the BMS sales force focus on the clinical issues in marketing Paraplatin against generic cisplatin so as not to be dragged into the practice economics implications. It was felt that highlighting the economic issues and generating related printed materials would lend too much credence to practice economics in the face of what was believed to be the compelling clinical rationale to continue dispensing Paraplatin. Emphasizing Paraplatin's efficacy, tolerability and quality of life benefits was the primary focus of the recommended sales force strategy.

8. As "[v]arying the prices of Paraplatin and Platinol [did] not have a material effect on prescribing practices,"[15] it was recommended that BMS "[e]mphasize [its] current promotional message—'Paraplatin is the better tolerated platinum agent'—particularly to at-risk practices."[16] For hospitals and community oncologists that had a "knee-jerk response to generic cisplatin," i.e., at-risk hospitals and practices who would deconvert to generic cisplatin from Paraplatin because of the acquisition cost advantage, it was recommended that BMS respond

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13 Plaintiffs' Memorandum, p. 22 and BMS/AWP/01233134.

14 BMS/AWP/01233134.

15 BMS/AWP/01233152.

16 BMS/AWP/01233172. See also BMS/AWP/01233154.

to questions about the financial implications of purchasing Paraplatin.[17] In particular, it was recommended that the BMS Oncology sales representatives should "not directly convey an economics message but are to refer these issues to the associate directors of sales operations."[18] As noted above, it was felt that a discussion by the sales force about the practice economics would be a distraction from the key marketing and sales strategy of promoting Paraplatin based on its efficacy, tolerability and quality of life benefits.

I declare under penalty of perjury that the foregoing is true and correct.
Executed on April 28, 2006

Gregory K. Bell

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17 BMS/AWP/01233172.

18 BMS/AWP/01233184.